K113477

JAN - 6 2012

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Kalamazoo, MI 49001
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510(k) Summary

510(k) Owner:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 (p) 269-323-7700 (f) 269-324-5412
Contact Person:	Christina McKee
Registration No.:	1811755
Trade Name:	Stryker® iVAS Balloon Catheter
Common Name:	Inflatable Bone Tamp
Classification Name:	Arthroscope Cement, Bone, Vertebroplasty
Regulation Number:	§888.1100 §888.3027
Product Code:	HRX NDN
Predicate Device:	Stryker® iVAS Balloon Catheter (K103807) Stryker® iVAS Balloon Catheter (K093419) Kyphx Xpander Inflatable Bone Tamps (K041454)
Device Description:	The Stryker® iVAS balloon catheter is a bone tamp with an inflatable component (balloon) at the distal end. The balloon is inflated to create a void within the vertebral body.
Indications for Use:	The Stryker® iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.
Testing:	The Stryker® iVAS balloon catheter meets the specification and performance characteristics and are substantially equivalent to the predicate devices. The testing which was conducted included functional testing, such as insertion and retraction force, force to puncture, burst and simulated use.

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Biocompatibility:	Biocompatibility testing of the Stryker® iVAS balloon catheter confirmed that the device meets the applicable requirements of the FDA Blue Book Memorandum G95-1 entitled Use of International Standards ISO-10993 Biological Evaluation of Medical Devices Part -1: Evaluation and Testing and are biocompatible.
Substantial Equivalence (SE) Rational:	The Stryker® iVAS balloon catheter is substantially equivalent in intended use, technological characteristics, safety, and effectiveness to the Stryker® iVAS Balloon Catheter and the Kyphx Xpander Inflatable Bone Tamp. The products have the same fundamental scientific technology, basic design, functional characteristics and the same clinical applications.
Safety and Effectiveness:	The Stryker® iVAS balloon catheter does not raise any new safety and efficacy concerns when compared to a similar device already legally marketed. Therefore, the Stryker® iVAS balloon catheter is equivalent to the existing predicate devices.
Submitted by:	Christina McKee Regulatory Affairs Associate Analyst
	_____ Signature
Date Submitted:	_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 6 2012

Stryker Instruments
% Ms. Christina McKee
Regulatory Affairs Supervisor
4100 E. Milham Ave
Kalamazoo, Michigan 49001

Re: K113477
Trade Name: iVAS 20mm (10 Gauge) Balloon Catheter
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: November 22, 2011
Received: November 23, 2011

Dear Ms. McKee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): _____

Device Name: Stryker Inflatable Vertebral Augmentation System (iVAS)

Indications for Use

The Stryker® iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.

Prescription Use ____X____ and/or Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113477